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PATENT APPLICATION

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Paul A. Renhowe, et al.

Serial No.: 09/943,382

Filed: August 30, 2001

Title: **HETEROCYCLIC COMPOUNDS**

Docket No.: 072121:0139

Commissioner for Patents
Washington, D.C. 20231

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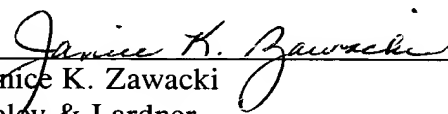
I hereby certify that these attached documents, transmitted via facsimile to the U.S. Patent and Trademark Office on October 17, 2002,

- * Facsimile coversheet dated October 17, 2002
- * Petition for Extension of Time (duplicate)
- * Response to Restriction Requirement (duplicate of pages 1, 2, and signature page)

and the attached Return Postcard

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Commissioner for Patents, Washington, D.C. 20231.

Enclosed for filing please find the above-referenced documents. Please indicate receipt of these documents by returning the attached postcard with the official Patent and Trademark Office receipt stamped thereon.


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Atty. Dkt. No. 072121-0139

PATENT APPLICATION

#15
11/1/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Paul A. RENHOWE, *et al.*
Title: HETEROCYCLIC COMPOUNDS
Appl. No.: 09/943,382
Filing Date: 08/30/2001
Examiner: R. Desai
Art Unit: 1625

CERTIFICATE OF FACSIMILE TRANSMISSION I hereby certify that this correspondence is being transmitted via facsimile to the United States Patent and Trademark Office, Washington D.C. on the date below. Bernard P. Friedrichsen (Printed Name) (Signature) October 17, 2002 (Date of Deposit)
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RESPONSE TO RESTRICTION REQUIREMENT

Commissioner of Patents
Washington, D.C. 20231

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Dear Sir or Madam:

This is in reply to an Office Action purportedly mailed on April 17, 2002, imposing a restriction requirement in the above-captioned application. The shortened one month statutory period for response to the Office Action expired on May 17, 2002. Applicants did not receive the mailed copy of the Office Action and only became aware of it yesterday, October 16, 2002, when the status of this application was checked using PAIR. With the Attached Petition for Extension of Time and the Authorization to Charge Deposit Account No. 50-2350 for the fee for five-month extension of time, this response is timely filed. However, Applicants respectfully request that the fees be waived because they did not receive the mailed copy of the restriction requirement and first became aware of it using the PAIR system on October 16, 2002. Because Applicants did not become aware of the office action until October 16, 2002, Applicants additionally request that any Patent Term Adjustment (PTA) not be negatively impacted by the delay in filing this response.

Applicants thank Examiner Desai for her responsiveness in immediately transmitting a copy of the outstanding Office Action by facsimile to

them on October 16, 2002, after Applicants advised her that they had not received a copy of the Office Action.

Applicants believe no fees in addition to the five-month extension of time fees are due for this filing. However, should any fees be due, the Patent Office is hereby authorized to charge any additional fees required for this filing or credit any overpayment to Deposit Account No. 50-2350. For the purpose of charging or crediting said deposit account, duplicates of pages 1 and 2 and the signature page of this response are submitted herewith.

In response to the restriction requirement, Applicants provisionally elect the claims and compounds of Group III (claims 1-8 and 18) for examination with traverse. Applicants provisionally elect the species 4-amino-3-[5-(4-methylpiperazin-1-yl)-1H-benzimidazol-2-yl]-1,7-naphthyridin-2(1H)-one for examination. This compound is specifically disclosed in the patent application as described in greater detail below. The claims of Group III that read on the elected species include claims 1, 2, 3, 4, and 18.

A Applicants hereby cancel claims 9-17, 20, ✓ and 21 without prejudice to Applicants' rights to pursue such claims in a timely filed divisional or continuation application.

REMARKS

In the Office Action, a restriction requirement was imposed under 35 U.S.C. § 121 between the claims of Groups I, II, III, IV, V, and VI described in greater detail below:

I. Claims 1-8 and 18 all in part, drawn to compounds and pharmaceutical compositions of compounds of formula I wherein Y is $\text{NR}^{10}\text{R}^{11}$, OH, OR⁸, Z is NR¹³, R¹ and R² do not together form a ring, all other R are non-hetero ring containing, classified in class 546, 514, subclass 272.8, 268.4, 322. The Examiner required further election of a single disclosed species. With respect to Group I, Applicants respectfully note that claim 1 specifically sets forth that, "R¹ and R² join to form a 5 to 7 membered substituted or unsubstituted ring comprising at least one O, N, or S atom." Therefore,

Applicants respectfully submit that Group I, as defined by the Examiner, is improper.

II. Claims 1-8 and 18 all in part, drawn to compounds and pharmaceutical compositions of compounds of formula I wherein Y is $\text{NR}^{10}\text{R}^{11}$, OH, OR^8 , Z is NR^{13} , R^1 and R^2 , together form a ring, containing S or O as a hetero atom all other R are non-hetero ring, classified in class 546, 514, subclass 114, 115, 300. The Examiner required a further election of a single disclosed species with respect to Group II.

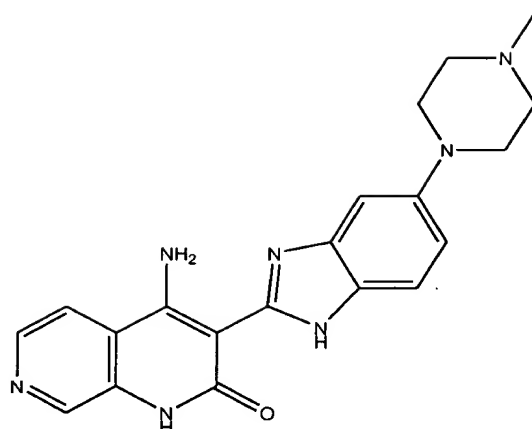
III. Claims 1-8 and 18 all in part, drawn to compounds and pharmaceutical compositions of compounds of formula I other than in Groups I and II, classified in various classes and subclasses. The Examiner required a further election of a single disclosed species with respect to this Group. The Examiner also noted that this group may be subject to further restriction.

IV. Claims 9-17 and 20 in part, drawn to compounds and pharmaceutical compositions of compounds of structure III wherein X^4 is N, one of W^1 to W^4 is a N, Y is a H, OH, OR^{10} , $\text{NR}^{12}\text{R}^{13}$ and all other R groups are non-hetero ring containing, classified in class 546, 514, subclass 113, 300.

V. Claims 9-17 and 20 in part, drawn to compounds and pharmaceutical compositions of compounds of structure III not found in Group IV, classified in class 546, 514 in various subclasses. The Examiner required a further election of species for this group. The Examiner also indicated that this group may be subject to further restriction.

VI. Claims 19 and 21, drawn to methods of treating diseases using these compounds classified in class 514 and various subclasses. The Examiner noted that this group may be subject to further restriction.

As noted above, Applicants hereby provisionally elect the claims and compounds of Group III for prosecution with traverse. The Examiner required that a species be elected for prosecution. Applicants provisionally elect the species 4-amino-3-[5-(4-methylpiperazin-1-yl)-1H-benzimidazol-2-yl]-1,7-naphthyridin-2(1H)-one for examination. The structure of this compound follows:



This compound is specifically disclosed in the patent application in paragraph [0233] which starts on page 88. The elected species is listed on page 89 and is the twelfth compound listed in paragraph [0233] (the ninth compound listed on page 89).

Group I specifies that R¹ and R² do not join together to form a ring. In the elected species, R¹ and R² join together to form a ring. Therefore, the elected species is not a member of Group I as defined by the Examiner. Group II specifies that R¹ and R² together form a ring containing S or O as a heteroatom. In the elected species, R¹ and R² form a ring that includes N, but does not include S or O as a heteroatom. For this reason, the elected species is not a member of Group II as defined by the Examiner. As defined by the Examiner, the claims of Group III are directed to compounds and pharmaceutical compositions of structure I of claims 1-8 and 18 other than those of Groups I and II. Because the elected species is not a member of Group I or Group II, but falls within the scope of independent claim 1, the elected species is a member of Group III. The claims of Group III that read on the elected species include claims 1, 2, 3, 4, and 18.

Groups II and III are both directed to claims 1-8 and 18 for compounds of structure I and pharmaceutical formulations that include the compounds. Claim 19 of Group VI is directed to a method of treating a patient that comprises administering an effective amount of the pharmaceutical formulation of claim 18 to a patient. Because each of these claims is directed to a compound of structure I (as defined by independent claim 1), a pharmaceutical

formulation that includes a compound of structure I (as defined by independent claim 1), or a method of treating a patient using a pharmaceutical formulation that includes a compound of structure I (as defined by claim 1), Applicants respectfully contend that these claims should be examined together in one application. With respect to claim 19 of Group VI, Applicants respectfully contend that if the compounds of claim 1 are found to be novel and non-obvious, then the pharmaceutical formulation of claim 18 will be novel and non-obvious and so will the method of treating set forth in claim 19. For this reason, Applicants respectfully request that the compounds, pharmaceutical formulations, and methods of treating set forth in Groups II, III, and claim 19 of Group VI be examined together in the same application.

According to § 803 of the MPEP, two criteria must be met for any restriction requirement to be proper. First, the inventions must be independent or distinct as claimed. Second, there must be a serious burden on the Examiner. As stated in § 803 of the MPEP, "If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

Applicants understand and appreciate the Examiner's time constraints in examining applications. However, Applicants respectfully contend that the search and examination of the claims of Groups II, III, and claim 19 of Group VI, should be possible without imposing a serious burden upon the Examiner.

CONCLUSION

Applicants respectfully request that the restriction requirement imposed between Groups II and III be reconsidered and withdrawn and that claims 1-8 and 18 of the application be examined together in their entirety as filed. Applicants further request that the claims of Groups II, III, and claim 19 of

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Group VI be reconsidered and withdrawn and that claims 1-8, 18, and 19 be examined together in their entirety as filed.

Respectfully submitted,

Date October 17, 2002

By 

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